Statement of Chairman Tom Davis Committee on Government Reform Hearing on "Harnessing Science: Advancing Care by Accelerating the Rate of Cancer Clinical Trial Participation" May 13, 2004

Good morning. I would like to welcome everyone to today's oversight hearing on cancer clinical trials. This hearing will examine the status of efforts to bring innovative cancer treatments to patients and discuss how to change the face of cancer into a less terminal and more treatable disease. The two panels of witnesses today will present testimony on the various factors contributing to low accrual of adult patients in cancer clinical trials and what efforts are being taken to obtain reasonable participation levels to better provide more treatment options to cancer patients.

Cancer is the second leading cause of death in the United States, taking the lives of over half a million Americans each year, or more than 1,500 people per day. Roughly 1.3 million new cancer cases are diagnosed in this country each year. These statistics are sobering. All of us here today know a relative or friend who has been diagnosed with some type of cancer. Anyone who has been affected by cancer understands the need for more and better treatment options for patients. And in order for new drugs and therapies to be approved by the Food and Drug Administration, several cancer clinical trials must be conducted.

Clinical trials are essential for determining safe and effective therapies in modern medicine. Early detection of cancer and the application of new treatments developed through clinical research are responsible for significant improvements in cancer survival rates. Clinical trials are designed to answer scientific questions, which translate into better and less toxic therapies for patients. Trials allow doctors and researchers to gain information about the benefits, side effects, possible applications, and doses of new and existing drugs.

In order for scientists and oncologists to make accurate conclusions about an experimental new drug's effects, clinical trials require the participation of numerous cancer patients. Further, research has shown that trial participants nearly always receive equivalent or better care than those receiving standard treatments, despite the experimental nature of these investigational treatments. Clinical trials can offer patients advanced treatment that would otherwise be unattainable. Thousands of people are helped each year by joining cancer clinical trials, and millions of people have ultimately benefited from others' participation in trials. So we pose the question to our panels of witnesses today: why do only 3% of adults nationwide enroll in clinical trials when up to 20% are eligible? And what efforts are being taken to resolve the barriers to better clinical trials and adequate adult enrollment?

We want to examine the different scientific, logistical and financial realities that interact to impede reasonable participation in adult trials. The lack of patient and physician education about clinical trials, problems traveling to trial sites, strict eligibility

criteria, and third-party payer reimbursement policies prevent a large number of patients from participating. As a result of these contributing factors, a vast majority of cancer patients fail to even consider clinical trials when reviewing their treatment options. We will hear today from the cancer community the urgency to reverse this situation and resolve the barriers to adequate adult enrollment in clinical trials.

Clinical trials are essential for improving outcomes in cancer patients. By improving participation levels and creating more trials to test new therapies, we can transform cancer into a more treatable and less fatal disease. The equation is simple: clinical research leads to the discovery of new and better therapies for cancer patients, helping them live longer and improving their quality of life.

I'm sure all of our witnesses this morning will agree that we need to boost participation in clinical trials. Along with improving accrual rates, we may need to consider improving other ways our health community approaches cancer. Clinical trials are just a single component to the cancer spectrum. I understand the complexity of the disease and the intricacies surrounding the discovery, development, and delivery of treatments. I look forward to a constructive dialogue on this topic. The Committee welcomes our witnesses and their important testimony today.